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AMENDMENT 1
2005-07-01

Dental base metal casting alloys —

Part 2:

Nickel-based alloys

AMENDMENT 1

Alliages dentaires non précieux à couler —

Partie 2: Alliages à base de nickel

AMENDEMENT 1



Reference number
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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to ISO 6871-2:1994 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

Dental base metal casting alloys —

Part 2: Nickel-based alloys

AMENDMENT 1

Page iv, Introduction

Replace the text in the Introduction with the following text:

“Dental base metal casting alloys are suitable for use in fabrication of removable dental appliances. Specific qualitative and quantitative requirements of freedom from biological hazards are not included in this part of ISO 6871 but when assessing possible biological or toxicological hazards, it is recommendable to refer to ISO 7405 and ISO 10993-1.

For other compositions, the manufacturer has to present adequate evidence of biological investigations in accordance with ISO 7405 or ISO 10933-1, and/or clinical investigations in order to assess the biological response of the material.

Specific quantitative requirements for corrosion resistance are not included in this part of ISO 6871. In order to obtain information on the kind and amount of metal ions leached from the alloy, see ISO 10271, and the static immersion test, described in Annex A.”

Page 1, Clause 2

Replace the following normative references with the latest editions:

“ISO 6892:1998, *Metallic materials — Tensile testing at ambient temperature*

ASTM B600-91(2002), *Standard guide for descaling and cleaning titanium and titanium alloy surfaces*”

Page 1, subclause 4.1

Replace subclause 4.1 with the following text:

“The chemical composition of the casting alloy shall meet the following requirements:

Nickel	main constituent
Chromium	≥ 20 % [mass fraction ¹⁾]
Molybdenum	≥ 4 % (mass fraction)
Cobalt + nickel + chromium	≥ 85 % (mass fraction)

1) The unit (*ml/m*) is deprecated. In accordance with ISO 31-0:1992, 2.3.3, Note 4, the correct expression is mass fraction.

The alloy shall not contain more than 0,02 % (mass fraction) of beryllium.

Constituents of the alloy in excess of 20 % (mass fraction) shall be within 2 % (mass fraction) of the value stated [see Clause 8 b) and 9.2 d)]. Constituents in excess of 2 % (mass fraction) but not in excess of 20 % (mass fraction) shall be within 1 % (mass fraction) of the value stated [see Clause 8 b) and 9 d)]. The percentage of nickel shall not be greater than the percentage indicated on the package label or insert (see Clause 8).

Page 3, Clause 8 b)

Replace Clause 8 b) with the following text:

- "b) a list of all elements present in concentrations equal to or greater than 0,1 % (mass fraction), and their percentage concentration (mass fraction) if present in concentrations equal to or greater than 2 %."

Pages 3 and 4, Clause 8, last paragraph

Replace the last paragraph of Clause 8 with the following text:

"As the alloy contains nickel, this shall be clearly stated on the package."

Page 4, subclause 9.2 g)

Replace subclause 9.2 g) with the following text:

- "g) a **WARNING** that the alloy contains nickel and, if it contains any other hazardous element, the warning shall identify the elements and state the percentage (mass fraction) in which they are present."

Page 6, Annex B

Delete Annex B.

Page 7, Annex C

Delete "Annex C (informative)" so that it reads simply "Bibliography".

Replace the following references with the latest editions:

- [1] ISO 1942, *Dentistry — Vocabulary*²⁾
- [2] ISO 7405:1997, *Dentistry — Preclinical evaluation of biocompatibility of medical devices used in dentistry — Test methods for dental materials*
- [3] ISO 10271:2001, *Dental metallic materials — Corrosion test methods*
- [4] ISO 10993-1:2003, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

2) To be published. (Revision of ISO 1942-1:1989, ISO 1942-2:1989, ISO 1942-3:1989, ISO 1942-4:1989 and ISO 1942-5:1989)